

IN THE CLAIMS

Please amend the claims as follows:

1. (Currently Amended) A patch device adapted for use in the transdermal administration to a patient of a composition including, or consisting of, dimethylformamide (DMF), the patch consisting of a layered construct adapted to be adhered to the skin of a patient and defining a depot cavity for the composition to be administered between a proximal layer and a distal layer thereof, which proximal layer is adapted in use to be located in intimate contact with the skin of the patient and which distal layer is in use disposed on the outer side thereof, the distal layer being characterized in that it comprises a composite layer having a first layer which is flexible and made of an elastomeric silicone material which is partially permeable to the composition to be administered; and a second layer which is impervious to said composition, and the proximal layer being characterised in that it is flexible and made of said elastomeric silicone material and is partially permeable to the composition, so that in use the composition may be disposed in the cavity and permeates from there through the proximal layer to be absorbed through the skin into the body of the patient, the proximal and distal layers being bonded to portions of each other by means of silicone adhesive or by vulcanizing, the proximal layer being further characterized in that its permeability to the irritating substance or component of the composition to be administered to the human or animal is less than the permeability of the human or animal skin, as the case may be, to such irritating substance or component, thereby to reduce irritation of the human or animal skin.
2. (Cancelled)
3. (Cancelled)
4. (Previously Presented) The patch of claim 1 suitable for use in the administration of DMF to a patient and characterized in that the proximal layer of the patch has a permeability to DMF, such that DMF which is, in use, located in the cavity between the layers will be released through the proximal layer at a rate below the rate which it is absorbed through the skin of the patient to which the patient is in use applied, thereby substantially preventing building up of DMF in direct contact with the skin of the patient.
5. (Previously Presented) The patch of claim 1 which is adapted to be adhered to the skin of a patient by having a peripheral edge zone of the proximal layer which is provided with a

pharmaceutically acceptable adhesive layer, which adhesive layer is covered by means of a conventional peel-off cover sheet during storage.

6. (Previously Presented) The patch of claim 4 in which the layers of a patch intended to be used for the administration of dimethylformamide as such, or of a pharmaceutical preparation containing dimethylformamide as a penetration enhancing agent, are of the same chemical composition and are made from vulcanizates of silicone.

7. (Previously Presented) The patch of claim 4 wherein the composition of the layer intended for use as a proximal layer in a patch for use in the administration of DMF as such, or of a pharmaceutical preparation containing DMF as a penetration enhancing agent, is produced to have permeability to dimethylformamide of not more than 9 mg DMF/cm²/hour.

8. (Previously Presented) The patch of claim 1 in which the cavity defined between the proximal and distal layers of the patch construct is preferably in use filled with a solid filler material to serve as a carrier for the pharmaceutically active substance or composition received therein.

9. (Previously Presented) The patch of claim 1 characterized in that it provides a passage through the distal layer or layers, through which passage of the substance or composition to be administered to the patient may in use be introduced into the cavity of the patch after the patch has been placed on the patient.

10. (Previously Presented) The patch of claim 9 wherein the passage is in part constituted by a self reclosing nipple or port formation integrally moulded with the distal layer of the patch construct, or part thereof, to present an access opening on the outer surface of the patch into which the sprout-like needle mounting of a conventional syringe may in use be received to introduce the substance or composition to be administered into the cavity via the passage.

11. (Previously Presented) The patch of claim 1 wherein the construct further includes a self adhesive mounting layer having a surface presenting a skin adhesive which adhesive layer is typically during pre-use storage the product covered by a peelable cover layer also overlies, and hence seals off, the proximal layer of the construct until it is exposed by peeling off the cover layer.

12. (New) A method for administering a drug transdermally, comprising:

depositing the drug in a cavity formed between a distal layer and a proximal layer of a transdermal patch; wherein the distal layer is impermeable to the drug, and the proximal layer is permeable to the drug and adapted to be in contact with human skin; and

reducing irritation of the human skin due to components of the drug by preventing build up of the drug between the proximal layer and the human skin.

13. (New) The method of claim 12, wherein the preventing the build up of the drug comprises reducing the permeability of the proximal layer to the drug to below the permeability of human skin to the drug.